IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES BEFORE JUDGE GOODWIN:

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Robert D. Moore, D.O.)

Pending in *In re C. R. Bard, Inc.*, *2:10-md-2187*, MDL 2187, is the *Daubert* Motion to Exclude or Limit Certain Opinions and Testimony of Robert D. Moore, D.O. [ECF No. 4581] filed by defendant C. R. Bard, Inc. ("Bard"). The motion is now ripe for consideration because the briefing is complete. As set forth below, Bard's motion is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

I. Background

his case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 1,500 of which are in the Bard MDL, 2187 MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara

J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, a docket control order subjects each case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 236 (establishing Wave 4); PTO # 244 (establishing Wave 5). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure for cases designated in Wave 4 and Wave 5. The court instructed the parties to file briefing on general causation issues in the main MDL, MDL 2187, while specific causation *Daubert* motions, responses, and replies were to be filed in the individual member cases. To the extent that an expert is both a general and specific causation expert, the court advised the parties that they could file a general causation motion in the main MDL and a specific causation motion in an individual member case. *See* PTO # 236, at 4; PTO # 244, at 4.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and

(1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct" – "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness"

> standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted). At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

III. Discussion

Dr. Robert D. Moore is a board-certified urogynecologist with a subspecialty in female pelvic medicine and reconstructive surgery. The plaintiffs offer Dr. Moore as an expert witness on Bard's Align TO product. Bard makes several objections to Dr. Moore's proposed testimony, discussed below.

A. Legal Conclusions

First, Bard seeks to exclude as improper legal conclusions Dr. Moore's opinions that the Align TO is "defective" and "unreasonably dangerous," and that it "failed to warn" physicians and provided inadequate instructions. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *See, e.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Therefore, to the extent it seeks to exclude Dr. Moore's legal conclusions, Bard's motion is **GRANTED**.

B. Opinions Criticizing Implanting Surgical Technique

Bard states that Dr. Moore's opinion regarding the surgical technique used to implant the Align TO is irrelevant because it is not a criticism of the device itself and, as a result, should be excluded. The relevance of a matter like this is best assessed in context during trial, so I **RESERVE** ruling on this matter for trial.

C. Opinions Regarding Product Design

Next, Bard argues that Dr. Moore should not be permitted to offer certain opinions on the design and alleged complications of the Align TO product because they are unreliable. The basis of this claim is that Dr. Moore relies solely on his personal clinical experience and that he fails to provide any scientific literature or study to support his testimony on this subject. I disagree.

As an initial matter, Dr. Moore's expansive academic and clinical experience render him clearly qualified to address the design and alleged complications of the Align TO. As stated in his expert report, Dr. Moore has been practicing in the field of Urogynecology and Pelvic Reconstructive Surgery for over seventeen years. *See* Def.'s Mot. to Exclude or Limit Certain Ops. & Test. of Robert D. Moore, D.O., Ex. B ("Dr. Moore's Expert Report"), at 2 [ECF No. 4581-2]. Dr. Moore completes between 400 and 500 urogynecologic procedures per year. *Id.* at 5. He has implanted over 1,000 slings in his career and approximately 500 or more vaginal mesh implants. *Id.* Dr. Moore has also explanted more than 700 mesh devices, including Align TO slings. *Id.*

at 6. Dr. Moore presented three abstracts at the 2014 combined American Urogynecology Society and International Urogynecology Society Meeting on mesh complications and female reconstructive surgery, two of which were published in a peer-reviewed medical journal. *Id.* at 5. In fact, this court has characterized Dr. Moore's studies as "the largest, most comprehensive known studies in the world regarding mesh complications." *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582206, at *2 (S.D. W. Va. 2016). Therefore, I **FIND** Dr. Moore qualified to opine on matters related to product design.

Second, Bard's contention that Dr. Moore should be precluded from testifying on this matter because he neglected to identify any studies or reports supporting his clinical observations is without merit. *See Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989) ("Generally, the test for exclusion is a strict one, and the purported expert must have neither satisfactory knowledge, skill, experience, training nor education on the issue for which the opinion is proffered."); *Kingsley v. Brenda & Gene Lummus, Inc.*, No. 1:11-CV-32, 2012 WL 727091, at *7 (W.D.N.C. Mar. 6, 2012) (stating that *Daubert* requires at bottom an "explanation . . . sufficient to permit others with similar training and experience to review his opinions and subject them to scientific testing"). In fact, as stated by the plaitniffs, Dr. Moore testified at length describing the methodology of his opinions on this subject. *See* Pls.' Resp. in Opp'n to Def.'s Mot. to Exclude or Limit Certain Ops. of Robert D. Moore, D.O. ("Pls.' Resp."), at 9 [ECF No. 4601] (citing Def.'s Mot. to Exclude or Limit Certain Ops. & Test. of Robert D. Moore, D.O., Ex. D ("Dr. Moore's Dep."), at 100:5 – 117:16

(supporting his opinion that blind passage of trocars through multiple muscles and tissue results in tissue damage); 117:17 – 125:23 (explaining how certain product defects result in mesh deformation, roping and curling) [ECF No. 4581-2]. Therefore, I **FIND** Dr. Moore's testimony on this topic reliable.

Finally, Bard objects to the admission of Dr. Moore's opinion that the sheath of the Align TO product is difficult to remove. The basis of this claim is Dr. Moore's acknowledgment that he has never removed an Align TO sheath, and his admission that he considered Bard's internal studies in forming this opinion. I agree Dr. Moore simply cannot parrot the substance of a corporate document and present its conclusions as expert testimony. However, I am not persuaded that this is the intention of Dr. Moore's testimony on this matter. Nor is it conclusive that Dr. Moore relies solely on Bard's internal documents to support his viewpoint. Because nothing under *Daubert* prevents an opposing expert from considering internal corporate documents to form his or her opinions, there is no justification to exclude Dr. Moore's opinion on the design of the Align TO's sheath.

Thus, Bard's motion on this point is **DENIED**.

D. Opinions Not Contained in Expert Report

Bard also seeks to exclude Dr. Moore's expected criticism regarding the pore size of the Align TO under Rule 26 on the basis that it was not included in his expert report. *See* Fed. R. Civ. P. 26(a)(2)(B). If a report lacks "a complete statement of all opinions," then a party may not use "that information . . . to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is

harmless." Fed. R. Civ. P. 37(c). The plaintiffs do not offer any response to the defendant's argument, nor do they offer an argument that the failure was "substantially justified" or "harmless." I will not search for an explanation for the exclusion of this opinion, and I will not craft arguments for the plaintiffs. Accordingly, I **GRANT** Bard's motion on this point.

E. Opinions Concerning the Instructions for Use

Next, Bard seeks to exclude Dr. Moore's testimony regarding the Instructions for Use ("IFUs"), arguing that Dr. Moore is unqualified to give such opinions and that the opinions are based solely on his personal experience.

I have previously determined that Dr. Moore is qualified to opine on the sufficiency of IFUs to a certain extent.[1] *See Franco v. Boston Scientific Corp.*, No. 2:12-cv-2748, 2016 WL 3248505, at *16 (S.D. W. Va. 2016). "[D]octors are 'fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs] . . . and to compare that knowledge with what was provided in the text of labeling and warnings for FDA approved drugs.'" *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011)).

Here, Dr. Moore is qualified to opine on the content of the IFU to the extent that his opinions fit within the comparison described in *In re Yasmin*, and the

[1] Note that "IFU" is synonymous with "DFU."

plaintiffs concede that Dr. Moore's testimony at trial will be limited accordingly. *See* Pls.' Resp., at 15. Therefore, Bard's motion on this matter is **DENIED**.

Furthermore, *Daubert* permits an expert to rely heavily on his experience to form opinions. Therefore, I will not impose a blanket exclusion on Dr. Moore's opinions simply because they are based on his personal experience. To the extent Bard seeks to challenge the bases for Dr. Moore's opinion, it may do so during cross-examination. Thus, I **DENY** Bard's motion on this matter.

F. Opinions Regarding the Adequacy of Clinical Trials

Bard also asks the court to exclude Dr. Moore's testimony regarding the adequacy of the defendant's clinical trials. I doubt the relevance of testimony on the adequacy of Bard's clinical testing or of particular product development procedures and assessments. Such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. However, because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

G. Opinions Concerning Bard's Knowledge, Motives, or Corporate Conduct

Finally, Bard argues that I should preclude Dr. Moore from testifying as to Bard's knowledge or state of mind. I agree; experts may not testify about what other parties did or did not know. However, to the extent Bard seeks to exclude Dr. Moore's testimony about factual issues or the knowledge of the medical community in general, I disagree. Expert witnesses may properly offer opinions on these topics. Therefore,

Bard's motion is **GRANTED** to the extent that it seeks to exclude evidence regarding Bard's knowledge, intent, or other matters related to corporate conduct.

IV. Conclusion

For the reasons stated above, the court **ORDERS** that Bard's *Daubert* Motion to Exclude or Limit Certain Opinions and Testimony of Robert D. Moore, D.O. [ECF No. 4581] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:10-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 4, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

CIVIL ACTION NUMBER	Case Name
2:14-cv-03439	Kitchen v. C. R. Bard, Inc. et al.
2:14-cv-18890	McManus v. C. R. Bard, Inc. et al.
2:14-cv-21874	McCray v. C. R. Bard, Inc. et al.
2:14-cv-23401	Barber v. C. R. Bard, Inc. et al.
2:14-cv-28943	Smith et al. v. C. R. Bard, Inc. et al.
2:16-cv-01855	Eiffler v. Sofradim Production SAS et al.